

Message Text

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TAGS: BEXP, EINV, PK

SUBJECT: PHARMACEUTICALS; GENERIC NAME SCHEME

ABANDONED

SUMMARY: ON JANUARY 17 GOP PROMULGATED A COMPREHENSIVE NEW DRUG ACT REPLACING THE ACTS OF 1940 AND 1972. UNDER THE NEW LAW, ONLY SINGLE INGREDIENT DURGS WILL GENERALLY BE LISTED BY GENERIC NAMES. COMPOUND DRUGS WILL BE GENERALLY LISTED BY PROPRIETARY NAMES. ESTABLISHED PHARMACEUTICAL COMPANIES, INCLUDING SOME AMERICAN FIRMS, BELIEVE NEW LAW IS IMPROVEMENT OVER PREVIOUS LAWS. IMPLEMENTATION OF ITS TESTING AND ENFORCEMENT PROVISIONS REMAINS UNCERTAIN. END SUMMARY.

1. FEDERAL MINISTER FOR HEALTH, LABOUR AND SOCIAL WELFARE ANNOUNCED JANUARY 17 THAT GOP PRESIDENT HAD PROMULGATED THE DRUGS ORDINANCE, 1976 TO REGULATE THE IMPORT, EXPORT, MANUFACTURE, STORAGE, DISTRIBUTION AND SALE OF DRUGS. THIS ORDINANCE IMMEDIATELY REPLACES THE DRUGS ACT OF 1940 AND THE DRUGS (GENERIC NAMES) ACT OF 1972. A NATIONAL FORMULARY OF ALL THE DRUGS PERMITTED FOR MANUFACTURE, IMPORT AND SALE WILL BE MAINTAINED BUT ONLY SINGLE INDREDIENT DRUGS WILL GENERALLY BE LISTED BY GENERIC NAMES. THE MINISTER SAID THAT

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COMPOUND DRUGS WILL GENERALLY BE LISTED BY PROPRIETARY

NAMES.

2. THE NEW ORDINANCE ESTABLISHES A NUMBER OF CONTROLS WITH AN APPARENT PRIMARY PURPOSE OF MORE CENTRAL CONTROL OVER MANUFACTURE AND SALE OF DRUGS AS OPPOSED TO PRESENT SYSTEM UNDER WHICH THE PROVINCES ADMINISTER MOST CONTROLS. A CENTRAL LICENSING BOARD WILL ISSUE LICENSES FOR AND REGULATE DRUG MANUFACTURE.

A CENTRAL REGISTRATION BOARD WILL TEST DRUGS, CHECK PRICES AND REGISTER DRUGS FOR SALE IN PAKISTAN. CHEMISTS (PHARMACIES) WILL NOW HAVE A LEGAL OBLIGATION TO ASSURE THAT ANY ITEMS SOLD TO THE PUBLIC COME FROM LICENSED MANUFACTURERS. MANUFACTURERS WILL HAVE TO SUBMIT COST STRUCTURE DATA AND MUST ALLOCATE FIVE PERCENT OF PROFITS TO RESEARCH. PENALTIES ARE INCREASED WITH MANUFACTURE OF COUNTERFEIT DRUGS PUNISHABLE UP TO SEVEN YEARS IN PRISON OR \$10,000 OR BOTH AND FOR SUBSTANDARD DRUGS PUNISHMENT OF UP TO FIVE YEARS OR \$5,000 OR BOTH.

3. REGULATIONS UNDER THE NEW ORDINANCE REQUIRING NEW LICENSING OF MANUFACTURERS AND NEW REGISTRATION OF ALL DRUGS TO BE MANUFACTURED OR IMPORTED MAY CAUSE SOME IMMEDIATE PROBLEMS. PUBLIC ANNOUNCEMENTS IN JANUARY 21 NEWSPAPERS STATE THAT NEW LICENSE APPLICATIONS MUST BE SUBMITTED BEFORE FEBRUARY 4, 1976 AND NEW REGISTRATION APPLICATIONS SUBMITTED BEFORE FEBRUARY 7, 1976. THE REGISTRATION OF NEW DRUGS REQUIRES VERY EXTENSIVE PHARMACOLOGICAL, MANUFACTURING, QUALITY CONTROL AND OTHER DATA. IN ADDITION, CERTIFICATION MUST BE SUBMITTED FROM THE COUNTRY OF ORIGIN AND IF THE DRUG HAS BEEN INTRODUCED INTO THE U.S. OR U.K., CERTIFICATION IS REQUIRED FROM THESE COUNTRIES WITH RESPECT TO INDICATION, CONTRAINDICATION AND SIDE EFFECTS.

4. CONGEN KARACHI REPORTS THAT INITIAL REACTION OF PHARMACEUTICAL MANUFACTURERS - SOME OF THE LARGEST OF WHICH ARE AMERICAN - IS CAUTIOUSLY FAVORABLE TOWARDS NEW ORDINANCE. THEY WELCOME THE NEW PROHIBITIONS ON MISLABELING AND COUNTERFEITING AND NEW QUALITY CONTROL PROVISIONS. THEY EXPRESS SKEPTICISM THAT THE LIMITED OFFICIAL USE

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ENFORCEMENT PROVISIONS OF NEW ORDINANCE WILL BE EFFECTIVELY IMPLEMENTED. THE MANAGING DIRECTOR OF ONE U.S. FIRM SAID THAT GRATUITIES TO INSPECTORS MAY HAVE TO BE INCREASED.

5. COMMENT: ALTHOUGH THE MINISTER DENIED THAT THIS ORDINANCE INDICATED FAILURE OF THE 1972 GENERIC DRUG SCHEME, THE GOP ACTION DOES INDICATE IT WAS NOT WORKING

SATISFACTORILY. LICENSING AND CONTROL OF DRUG MANUFACTURE HAD PROVED INEFFECTIVE, AND THE GOP WAS BEING PLAGUED WITH COMPLAINTS OF SUBSTANDARD, SHORT-MEASURED AND USELESS DRUGS. WITH NO EFFECTIVE CONTROL OVER LOCAL DRUG MANUFACTURE, MANY "KITCHEN CHEMISTS" ENTERED THE MARKET WITH LOW QUALITY DRUGS. DRUGGISTS WERE HAPPY TO PUSH THESE SINCE THEY OFTEN OFFERED HIGHER PROFIT MARGINS. IT IS TOO EARLY TO TELL WHETHER THE NEW ORDINANCE WILL BE ANY MORE STRIGENTLY ENFORCED THAN THE OLD.

6. EMBASSY WILL POUCH NEWS ARTICLE AND ORDINANCE TO HARVEY WINTER, EB/CBA/BP.
BYROADE

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